

ATTORNEY DOCKET NUMBER: 2003080-0143 (SK-744-CON9)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:

Danishefsky et al.

Examiner:

Not yet assigned

Serial No.:

10/726,386

Art Unit:

1614

Filing Date:

December 2, 2003

Title:

SYNTHESIS OF EPOTHILONES, INTERMEDIATES, THERETO,

ANALOGUES AND USES THEREOF

Mail Stop: Amendments
Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

TRANSMITTAL LETTER

Enclosed are the following documents:

- 1. Form PTO-1449 (11 pages);
- 2. Information Disclosure Statement (6 pages);
- 3. Cited Art (267); and
- 4. Return Postcard

If any additional fees are required to be paid or if any overpayment has been made, please charge same to Deposit Account No. 03-1721.

Respectfully submitted,

C. Hunter Baker, M.D., Ph.D.

Registration No. 46,533

Choate, Hall & Stewart Exchange Place 53 State Street Boston, MA 02109 (617) 248-5000 (617) 248-4000

Dated: 2/3/2005

3799145

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner For Patents,

P.O. Box 1450, Alexandria, VA 22313

on February 3,

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Alexandria, VA 22313-1450

Sir:

STATEMENT UNDER 37 C.F.R. §§ 1.56, 1.97, & 1.98

Pursuant to the duty of disclosure under 37 C.F.R. §§ 1.56, 1.97 and 1.98, Applicant requests consideration of this Information Disclosure Statement.

Type of Statement

The present Information Disclosure Statement is:

- [] An original Information Disclosure Statement; or
- [X] A supplemental Information Disclosure Statement.

Certificate of Mailing

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John ...

Lisa A. Walsh

Typed or Printed Name of person signing certificate

Compliance with 37 CFR § 1.97

The present Information Disclosure Statement is being filed:

[X]	X] Pursuant to 37 CFR § 1.97(b); no fee or certification is required:				
	[]	Withi	n three months of the filing date of a national application other than		
		a conf	inued prosecution application under § 1.53(d);		
	[]	Withi	n three months of the date of entry of the national stage as set forth		
		in § 1.	491 in an international application;		
	[X]	Befor	e the mailing of a first Office action on the merits; or		
	[]	Befor	e the mailing of a first Office action after the filing of a request for		
		contir	nued examination under § 1.114.		
[]	Pursu	ant to 3	7 CFR § 1.97(c) after the dates listed above but before the mailing		
	date o	of any o	f a final action under § 1.113, a notice of allowance under § 1.311, or		
	an act	ion that	otherwise closes prosecution in the application; Applicant hereby		
	either	:			
	[]	Certif	ies that either:		
		[]	each item of information contained in the information disclosure		
			statement was first cited in any communication from a foreign		
			patent office in a counterpart foreign application not more than		
			three months prior to the filing of the information disclosure		
			statement; or		
		[]	That no item of information contained in the information		
			disclosure statement was cited in a communication from a foreign		
			patent office in a counterpart foreign application, and, to the		

knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; or

[]	Includes herewith the fee set forth in § 1.17(p). Please charge Deposit
Account No.	03-1721.

- [] Pursuant to 37 CFR § 1.97(d), after the mailing date of any final action under § 1.113, a notice of allowance under § 1.311, or an action that otherwise closes prosecution in the application; Applicant hereby both:
 - [] Certifies that either:
 - [] each item of information contained in the information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of the information disclosure statement; or
 - That no item of information contained in the information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing the certification after making reasonable inquiry, no item of information contained in the information disclosure statement was known to any individual designated in § 1.56(c) more than three months prior to the filing of the information disclosure statement.; and

[] Includes herewith the fee set forth in § 1.17(p).

Content of the Information Disclosure Statement

Applicant hereby makes of record in the above-identified application the reference(s) listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

Applicant includes copies of references as indicated below:

- [X] A copy of each cited reference not indicated with an asterisk is included;
- [] Copies of references indicated with an asterisk on the attached form PTO-1449 are not included pursuant to 37 CFR § 1.98(d) because they were previously provided to the United States Patent Office in an Information Disclosure Statement that complies with 37 CFR § 1.98(a)-(c) and was submitted in the following patent application that is relied upon in the present case for an earlier effective filing date under 35 USC § 120:

Serial Number	Filing Date	Status

[] Copies of English translations of one or more non-English references are included.

Applicant hereby makes the following additional information of record in the aboveidentified application:

Applicant certifies that the Information Disclosure Statement either:

- [X] Does not contain non-English language citations;
- [] Does contain non-English language citations, for which an English language abstract is submitted.

- [] Does contain non-English language citations which were cited on an International Search Report (a copy of which is enclosed herewith).
- [] Includes one or more translations of a non-English citation.

Remarks

The submission of this Information Disclosure Statement should not be construed as a representation that a search has been made.

The submission of this Information Disclosure Statement shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).

The submission of this Information Disclosure Statement shall not be construed as a representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

It is respectfully requested that:

- 1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;
- 2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited patent(s) and publication(s) has (have) been fully considered by the Patent and Trademark Office during the examination of this application; and
- 3. The citations for the patent(s) and publication(s) be printed on any patent which issues from this application.

Notwithstanding any statements by Applicants, the Examiner is urged to form his or her own conclusions regarding the relevance of the cited reference(s).

Respectfully submitted,

C. Hunter Baker, M.D., Ph.D.

Reg. No. 46,533

CHOATE, HALL & STEWART Exchange Place 53 State Street Boston, Massachusetts 02109 (617) 248-5000 (617) 248-4000

Date: 2/3/2005

3799109

FORM PTO-1 (REV. 8-83)	FEB 0 7 2005 Commaten	t and Trademark Office	ATTY. DOCKET: 2003080-0143 (SK-744-CON9)	IN RE APPLIC NO.: 10/726,3	CATION 386
NFORMATIO DISCUSSURE STATEMENT			APPLICANT: Danishefs	ky et al	
	veral sheets if necess		FILING DATE: DECEMBER 2, 2003	GROUP	:
U.S. PATENT	DOCUMENTS				
Examiner's Initials	U.S. Patent No.	Applicant	Issue Date	Class	Subclass
	5,021,430	Ksander, et al.	June 4, 1991	514	332
	5,917,084	Jiang, et al.	June 29, 1999	560	174
	5,969,145	Schinzer, et al.	October 19, 1999	548	110
	6,043,372	Schinzer, et al.	March 28, 2000	548	110
	6,156,905	Schinzer et al.	December 5, 2000	548	204
	6,262,094	Höfle, et al.	July 17, 2001	514	365
	6,284,781	Danishefsky, et al.	September 4, 2001	514	365
	6,288,237	Höfle, et al.	September 11, 2001	548	203
- W TO 7	6,291,684	Borzilleri, et al.	September 18, 2001	548	961
2 XV-12 ² .	6,302,838	O'Reilly et al	October 16, 2001	574	365
- X - W.J. A	6,303,342	Julien	October 16, 2001	435	76
	6,303,767	Betlach	October 16, 2001	536	23.2
	6,320,045	Kim, et al.	November 20, 2001	540	463
	6,350,878	Altmann, et al.	February 26, 2002	548	110
	6,359,140	Höfle, et al.	March 19, 2002	548	204
	6,365,749	Kim et al.	April 2, 2002	548	204
	6,380,227	Mutz	April 30, 2002	514	365
	6,380,394	Nicolaou	April 20, 2002	548	125
Alle San	6,380,395	Vite	April 30, 2002	548	146
	6,383,787	Schupp	May 7, 2002	435	183
	6,384,230	Mulzer	May 7, 2002	548	203
	6,387,927	Altmann	May 14, 2002	514	311
	6,399,638	Vite	June 4, 2002	514	366
CONTROL L	6,410,301	Julien	June 25, 2002	435	252.3
	6,419,692	Yang et al.	July 16, 2002	623	115
· AMIR.	6,441,186	Nicolaou et al.	August 27, 2002	548	204
-	6,457,303	Georg et al.	October 1, 2002	56	465
	6,515,017	Li et al.	February 4, 2003	514	449
	6,518,421	Li et al.	February 11, 2003	540	462
	6,525,197	Furstner et al.	February 25, 2003	544	310
	6,531,497	Nicolaou et al.	March 11, 2003	514	370

FORM PTO-1449 U.S. Department of Commerce		nerce	ATTY. DOCKET: 2003080-0143	IN RE APPLIC	ATION
(REV. 8-83)			(SK-744-CON9) NO.: 10/726,386		86
INFORMATIO	ON DISCLOSURE	STATEMENT	APPLICANT: Danishefs	ky et al	
(Use several sheets if necessary)			FILING DATE: DECEMBER 2, 2003	GROUP	
	6,537,988	Lee	March 25, 2003	514	221
	6,538,038	Pero et al.	March 25, 2003	514	731
	6,544,544	Hunter et al.	April 8, 2003	424	424
	6,576,651	Bandyopadhyay et al.	June 10, 2003	514	365
	6,593,115	Vite et al.	July 15, 2003	435	134
	6,596,875	White et al.	July 22, 2003	548	204
	6,603,015	Georg et al.	August 5, 2003	549	203
	6,603,023	Danishefsky et al.	August 5, 2003	549	346
	6,605,599	Vite et al.	August 12, 2003	514	63
	6,605,726	Mulzer et al.	August 12, 2003	548	202
	6,610,736	Klar et al.	August 26, 2003	514	450
	6,613,912	Hoefle et al.	September 2, 2003	548	204
	6,624,310	Hoefle et al.	September 23, 2003	548	204
	6,625,666	O'Reilly et al.	October 21, 2003	710	5
	6,686,380	Lee	February 3, 2004	514	365
	6,689,802	DiMarco et al.	February 10, 2004	514	365
	6,719,540	Regueiro-Ren et al.	April 13, 2004	417	365
	6,723,854	Danishefsky et al.	April 20, 2004	548	203
·	6,727,276	Lee	April 27, 2004	514	540
<u> </u>	6,730,699	Li et al.	May 4, 2004	514	449
	6,730,803	Iwasaki <i>et al</i> .	May 4, 2004	558	442
	6,780,620	Li et al.	August 24, 2004	435	117
	6,800,653	Regueiro-Ren et al.	October 5, 2004	514	365
U.S. PATENT	APPLICATIONS			<u> </u>	
Examiner's Initials:	Serial Number:	Applicant:	Publication Date:	Group:	Art Unit:
	2001/0031880	Borzilleri et al.	October 18, 2001		
	2001/0034452	Hoefle et al.	April 16, 2001		
	2001/0051356	Khosla	December 13, 2001		
	2002/0002162	Lee	January 3, 2002		

Commer			ATTY. DOCKET: 2003080-0143	IN RE APPLICATION NO.:
(REV. 8-83) Patent and		t and Trademark Office	(SK-744-CON9)	10/726,386
INFORMATIO	N DISCLOSURE	STATEMENT	APPLICANT: Danishefs	
(Use several sheets if necessary)			FILING DATE:	GROUP:
			DECEMBER 2, 2003	
	2002/0004229	Santi et al.	January 10, 2002	
	2002/0010328	Reeves et al.	January 24, 2002	
	2002/0028839	O'Reilly et al.	March 7, 2002	
	2002/0042109	Vite et al.	April 11, 2002	
	2002/0045220	Khosla et al.	April 18, 2002	
	2002/0045609	Ashley et al.	April 18, 2002	
	2002/0052028	Santi et al.	May 2, 2002	
	2002/0058286	Danishefsky et al.	May 16, 2002	
	2002/0058817	Danishefsky et al.	May 16, 2002	
	2002/0062030	White et al.	May 23, 2002	
	2002/0065295	Chu et al.	May 30, 2002	
	2002/0143026	Lombardo et al.	October 3, 2002	
	2002/0143038	Bandyopadhyay et al.	October 3, 2002	
	2003/0203938	Nicolaou et al.	October 30, 2003	
	2003/0203929	Ghosh	October 30, 2003	
	2003/0203876	Hoogevest	October 30, 2003	
	2003/0194787	Hofmann et al	October 16, 2003	
	2003/0191089	Regueiro-Ren et al.	October 9, 2003	
	2003/0187273	White et al.	October 2, 2003	
	2003/0187039	Favreau et al.	October 2, 2003	
	2003/0186983	Mastalerz et al.	October 2, 2003	
,	2003/0186965	Vite et al.	October 2, 2003	
	2003/0180760	Basch et al.	September 25, 2003	
·	2003/0176710	Klar et al.	September 18, 2003	
	2003/0176473	Taylor et al.	September 18, 2003	
	2003/0176368	Danishefsky et al.	September 18, 2003	
	2003/0176320	Li et al.	September 18, 2003	
	2003/0171596	Danishefsky et al.	September 11, 2003	
	2004/0023345	Vite et al.	February 5, 2004	
	2004/0024032	Voi et al.	February 5, 2004	

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(REV. 8-83)			(SK-744-CON9)	NO.: 10/726,386	
INFORMATION	ON DISCLOSURE	STATEMENT	APPLICANT: Danishefs		
(Use several sheets if necessary)			FILING DATE: DECEMBER 2, 2003	GROUP:	
	2004/0024033	O'Reilly et al.	February 5, 2004		
	2004/0030147	White et al.	February 12, 2004		
	2004/0038324	Atadja et al.	February 26, 2004		
	2004/0039026	Nicolaou et al.	February 26, 2004		
	2004/0044203	Wittman et al.	March 4, 2004		
	2004/0044221	Danishefsky et al.	March 4, 2004		
-	2004/0049051	Hoefle et al.	March 11, 2004		
	2004/0053910	Danishefsky et al.	March 18, 2004		
	2004/0053978	Lee et al.	March 18, 2004		
	2004/0053995	Danishefsky et al.	March 18, 2004		
	2004/0054186	Das et al.	March 18, 2004		
	2004/0054188	Kusters et al.	March 18, 2004		
	2004/0058899	Klimko	March 25, 2004		
	2004/0058969	Buchmann et al.	March 25, 2004		
	2004/0062810	Hunter et al.	April 1, 2004		
	2004/0063707	Bhide et al.	April 1, 2004		
	2004/0063708	Bhide et al.	April 1, 2004		
	2004/0063712	Salvati et al	April 1, 2004		
	2004/0063715	Paruch et al.	April 1, 2004		
	2004/0072760	Carboni et al.	April 15, 2004		
	2004/0072832	Bhide et al.	April 15, 2004		
	2004/0072835	Paruch et al.	April 15, 2004		
	2004/0072870	Nicolaou et al.	April 15, 2004		
	2004/0072882	Johnson et al.	April 15, 2004		
	2004/0076672	Hunter et al.	April 22, 2004		
	2004/0077696	Borzilleri et al.	April 22, 2004		
	2004/0082651	Wessjohann et al.	April 29, 2004		
	2004/0087610	Pardee et al.	May 6, 2004		
	2004/0087634	Hoefle et al.	May 6, 2004		
	2004/0092478	Rothermel et al.	May 13, 2004		

FORM PTO-14 (REV. 8-83)	Comm	epartment of erce and Trademark Office	ATTY. DOCKET: 2003080-0143 (SK-744-CON9)	NO.:	CATION
INFORMATIO	ON DISCLOSURES	STATEMENT	APPLICANT: Danishefs	10/726,386	
	(Use several sheets if necessary)		FILING DATE: GROUDECEMBER 2, 2003		P:
	2004/0092514	Velaparthi et al.	May 13, 2004		
	2004/0092560	Hoefle et al.	May 13, 2004		
	2004/0097516	Dwyer et al.	May 20, 2004		
	2004/0102451	Guzi et al.	May 27, 2004		
· · · · · · · · · · · · · · · · · · ·	2004/0102452	Guzi et al.	May 27, 2004		
	2004/0102495	Danishefsky et al.	May 27, 2004		
	2004/0106624	Guzi et al.	June 3, 2004		
	2004/0106985	Jang	June 3, 2004		
	2004/0116442	Guzi et al.	June 17, 2004		
	2004/0126379	Adolf et al.	July 1, 2004		
	2004/0127432	Nicolaou et al.	July 1, 2004		
	2004/0132146	Benigni et al.	July 8, 2004		
	2004/0133271	Jang	July 8, 2004		
_	2004/0132692	Sherrill et al.	July 8, 2004		
	2004/0132736	Guzi et al.	July 8, 2004		
	2004/0132754	Brandt et al.	July 8, 2004		
	2004/0142931	Vite et al.	July 22, 2004		
	2004/0142990	Hofmann et al.	July 22, 2004		
	2004/0152708	Li et al.	August 5, 2004		
	2004/0157897	DiMarco et al.	August 12, 2004		
	2004/0167083	Bosslet et al.	August 26, 2004		
	2004/0167097	Zhou et al.	August 26, 2004		
	2004/0176429	Li et al.	September 9, 2004		
	2004/0192621	Nihei et al.	September 30, 2004		
FOREIGN PA	TENT DOCUMENT	TS .			
Examiner's	Document No.	Country	Date	Translat	tion
Initials				Yes	No
	DE 195 42 986.9	Germany	17 November 1995		
	DE 196 39 456.2	Germany	25 September 1996		

FORM PTO-14	Comn		ATTY. DOCKET: 2003080-0143	IN RE APPLICATION	
(REV. 8-83)	EV. 8-83) Patent and Trademark Office		(SK-744-CON9)	NO.: 10/726,386	
INFORMATIO	N DISCLOSURE	STATEMENT	APPLICANT: Danishefs	ky et al	
(Use several sheets if necessary)			FILING DATE: DECEMBER 2, 2003	GROUP:	
	DE 196 45 361	Germany	30 April 1998		
	DE 196 45 362	Germany	30 April 1998		
	EP 1 440 973	Europe	July 28, 2004		
	EP 1 428 826	Europe	June 16, 2004		
	EP 1 407 784	Europe	April 14, 2004		
	EP 1 386 922	Europe	February 4, 2004		
	EP 1 080 082	Europe	October 6, 2004		
	WO 04/087045	International	October 14, 2004		
	WO 04/085421	International	October 7, 2004		
	WO 04/080458	International	September 23, 2004		
	WO 04/063151	International	July 29, 2004		
	WO 04/061116	International	July 22, 2004		
	WO 04/056832	International	July 1, 2004		
	WO 04/054624	International	July 1, 2004		
	WO 04/054622	International	July 1, 2004		
	WO 04/054514	International	July 1, 2004		
	WO 04/052401	International	June 24, 2004		
	WO 04/052361	International	June 24, 2004		
	WO 04/052237	International	June 24, 2004		
	WO 04/050089	International	June 17, 2004		
	WO 04/050057	International	June 17, 2004		
	WO 04/048372	International	June 10, 2004		
	WO 04/043954	International	May 27, 2004		
	WO 04/043454	International	May 27, 2004		
	WO 04/043400	International	May 27, 2004		
	WO 04/043363	International	May 27, 2004		
-	WO 04/035050	International	April 29, 2004		
114	WO 04/032923	International	April 22, 2004		
	WO 04/032872	International	April 22, 2004		
	WO 04/032866	International	April 22, 2004		

FORM PTO-14	Comm		ATTY. DOCKET: 2003080-0143	IN RE APPLICATION
REV. 8-83) Patent and Trademark Office		(SK-744-CON9)	NO.: 10/726,386	
INFORMATIO	N DISCLOSURE	STATEMENT	APPLICANT: Danishefs	ky et al
(Use several sheets if necessary)			FILING DATE: DECEMBER 2, 2003	GROUP:
	WO 04/030627	International	April 15, 2004	
	WO 04/030620	International	April 15, 2004	
	WO 04/028610	International	April 8, 2004	
	WO 04/028582	International	April 8, 2004	
-	WO 04/026877	International	April 1, 2004	
	WO 04/026872	International	April 1, 2004	
	WO 04/026867	International	April 1, 2004	
	WO 04/026310	International	April \$, 2004	
	WO 04/026229	International	April 1, 2004	
	WO 04/024735	International	March 25, 2004	
	WO 04/022560	International	March 18, 2004	
	WO 04/022080	International	March 18, 2004	
	WO 04/022062	International	March 18, 2004	
	WO 04/018635	International	March 4, 2004	
	WO 04/016269	International	February 26, 2004	
	WO 04/012735	International	February 12, 2004	
	WO 04/007476	International	January 22, 2004	
	WO 03/096975	International	November 27, 2003	
	WO 03/057830	International	17 July 2003	
	WO 02/096281	International	December 5, 2004	
	WO 02/046196	International	13 June 2002	
	WO 02/042432	International	30 May 2002	
	WO 02/032844	International	16 October 2001	
	WO 99/028324	International	10 June 1999	
	WO 99/003848	International	28 January 1999	
	WO 95/003035	International	2 February 1995	
	WO 93/010121	International	27 May 1993	

FORM PTO-1449	U.S. Department of Commerce	ATTY. DOCKET:	IN RE APPLICATION	
(REV. 8-83)	Patent and Trademark Office	2003080-0143 (SK-744-CON9)	NO.:	
INFORMATION D	ISCLOSURE STATEMENT	APPLICANT: Danishefsky <i>et al</i>		
	sheets if necessary)	FILING DATE: DECEMBER 2, 2003	GROUP:	
	Itmann et al., "Epothilone B and Its Analev. Med. Chem. 3:149, 2003.	ogs -A New Family of An	ticancer Agents" Mini-	
	aggiolini <i>et al.</i> , "Stereocontrolled Total S x, 25-Dihydroxyergocalciferol" <i>J. Org.</i> C		exycholecalciferol and	
Ba D	alog et al., "Stereoselective Syntheses an esmethylepothilone A Series: Some Surp 997).	d Evaluation of Compound		
Bi	ijoy et al., "Synthetic Studies Directed To	owards Epothilone A " Tet.	Lett. 39:209-212, 1998.	
	ollag et al., "Epothilones, a New Class of 5:2325-2333, 1995.	f MT-stabilizing Agents " (Cancer Research	
	ollag <i>et al.</i> , "Epothilones: Novel Microtu 7):867-873, 1997.	bule Stabilizing Agents" E.	xpert Opin. Invest. Drug	
I	hakraborty et al., "Radical-induced Open 04, 1998.	ing of Trisubstituted Epoth	ilones" Tet. Lett. 39:101	
M A	hakravarty et al., "Taxoid and Non-Taxo olecular Modeling Approach to Eludicat bstracts, 214th ACS National Meeting, Lemerican Chemical Society.	ion of a Common Pharmac	ophore" Book of	
	hou et al., "Quantitative Analysis of Dos fultiple Drugs or Enzyme Inhibitors" Adv	se-Effect Relationships The Combined Effects of by Enzyme Reg. 22:27-55, 1984.		
C	hou et al., "Design and Total Synthesis of hich Eliminate Xenograft Tumors to a Note: 4762-4767, 2003.	f a Superior Family of Epo	thiolone Analogues,	
Eı		xic Marine Agent That Stabilizes Microtubules Mor		
FI	etcher et al., "Structure of the Mitogen-I			
	iannakakou <i>et al.</i> , "Paclitaxel-resistant Hubulins" <i>J. Biol. Chem.</i> 272 (27):17118-1			
	aar, et al., "Discodermolide, A Cytotoxic otently Than Taxol", Biochemistry, 35: 2			
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Is	ofle et al., "Epothilone A and B – Novel olation, Crystal Structure, and Conforma 5:1567-1569, 1996.		=	

FORM PTO-144	U.S. Department of Commerce	ATTY. DOCKET: 2003080-0143	IN RE APPLICATION
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